(ii) Has available to it, by arrangement or otherwise, the services of a sufficient number of licensed doctors of medicine or osteopathy engaged in the practice of medicine or surgery in such area to assure that adequate peer review of the services provided by the various medical specialties and subspecialties can be assured;

(2) Is able, in the judgment of the Secretary, to perform review functions required under section 1154 in a manner consistent with the efficient and effective administration of this part and to perform reviews of the pattern of quality of care in an area of medical practice where actual performance is measured against objective criteria which define acceptable and adequate practice; and

(3) Has at least one individual who is a representative of consumers on its governing body.

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

State means the fifty states, the District of Columbia, Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands.

State law or fraud enforcement agency includes, but is not limited to:

(1) A state law enforcement agency;

(2) A state Medicaid fraud control unit (as defined in section 1903(q) of the Social Security Act); and

(3) A state agency administering (including those providing payment for services) or supervising the administration of a state health care program (as defined in section 1128(h) of the Social Security Act).

State licensing or certification agency includes, but is not limited to, any authority of a state (or of a political subdivision thereof) responsible for the licensing or certification of health care practitioners (or any peer review organization or private accreditation entity reviewing the services provided by health care practitioners), health care entities, providers, or suppliers. Examples of such state agencies include Departments of Professional Regulation, Health, Social Services (including State Survey and Certification and Medicaid Single State agencies), Commerce, and Insurance.

Voluntary surrender of license or certification means a surrender made after a notification of investigation or a formal official request by a Federal or state licensing or certification authority for a health care practitioner, health care entity, provider, or supplier to surrender the license or certification (including certification agreements or contracts for participation in Federal or state health care programs). The definition also includes those instances where a health care practitioner, health care entity, provider, or supplier voluntarily surrenders a license or certification (including program participation agreements or contracts) in exchange for a decision by the licensing or certification authority to cease an investigation or similar proceeding, or in return for not conducting an investigation or proceeding, or in lieu of a disciplinary action.

[78 FR 20484, Apr. 5, 2013, 78 FR 25860, May 6, 2013]

Subpart B—Reporting of Information

§ 60.4 How information must be reported.

Information must be reported to the NPDB as required under §§ 60.7, 60.8, 60.9, 60.10, 60.11, 60.12, 60.13, 60.14, 60.15 and 60.16 in such form and manner as the Secretary may prescribe.

§ 60.5 When information must be reported.

Information required under §§ 60.7, 60.8, and 60.12 must be submitted to the NPDB within 30 days following the action to be reported, beginning with actions occurring on or after September 1, 1990; information required under § 60.11 must be submitted to the NPDB within 30 days following the action to be reported, beginning with actions occurring on or after January 1, 1992; and information required under §§ 60.9, 60.10, 60.13, 60.14, 60.15, and 60.16 must be submitted to the NPDB within 30

days following the action to be reported, beginning with actions occurring on or after August 21, 1996. Persons or entities responsible for submitting reports of malpractice payments (§ 60.7), negative actions or findings (§ 60.11), or adverse actions (§ 60.12) must additionally provide to their respective state authorities a copy of the report they submit to the NPDB. Following is the list of reportable actions:

(a) Malpractice payments (§ 60.7);

(b) Licensure and certification actions (§§ 60.8, 60.9, and 60.10);

(c) Negative actions or findings (§ 60.11);

(d) Adverse actions (§ 60.12);

(e) Health Care-related Criminal Convictions (§ 60.13);

(f) Health Care-related Civil Judgments (§ 60.14);

(g) Exclusions from Federal or state health care programs (§ 60.15); and

(h) Other adjudicated actions of decisions (§ 60.16).

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§ 60.6 Reporting errors, omissions, revisions or whether an action is on appeal.

(a) Persons and entities are responsible for the accuracy of information which they report to the NPDB. If errors or omissions are found after information has been reported, the person or entity which reported it must send an addition or correction to the NPDB and, in the case of reports made under § 60.12 of this part, also to the Board of Medical Examiners, as soon as possible. The NPDB will not accept requests for readjudication of the case by the NPDB, and will not examine the underlying merits of a reportable action.

(b) An individual or entity which reports information on licensure or certification, negative actions or findings, clinical privileges, criminal convictions, civil or administrative judgments, exclusions, or adjudicated actions or decisions under § 60.8, § 60.9, § 60.10, § 60.11, § 60.12, § 60.13, § 60.14, § 60.15, or § 60.16 must also report any revision of the action originally reported. Revisions include, but are not limited to, reversal of a professional review action or reinstatement of a license. In the case of actions reported under § 60.9, § 60.10, § 60.13, § 60.14, § 60.15 or § 60.16, revisions also include whether an action is on appeal. Revisions are subject to the same time constraints and procedures of § 60.5, § 60.8, § 60.9, § 60.10, § 60.11, § 60.12, § 60.13, § 60.14, § 60.15, or § 60.16 as applicable to the original action which was reported.

(c) The subject will be sent a copy of all reports, including revisions and corrections to the report.

(d) Upon receipt of a report, the subject:

(1) Can accept the report as written;

(2) May provide a statement to the NPDB that will be permanently appended to the report, either directly or through a designated representative; (The NPDB will distribute the statement to queriers, where identifiable, and to the reporting entity and the subject of the report. Only the subject can, upon request, make changes to the statement. The NPDB will not edit the statement; however the NPDB reserves the right to redact personal identifying and offensive language that does not change the factual nature of the statement.); or

(3) May follow the dispute process in accordance with § 60.21.

[78 FR 20484, Apr. 5, 2013, 78 FR 25860, May 6, 2013]

§ 60.7 Reporting medical malpractice payments.

(a) *Who must report.* Each entity, including an insurance company, which makes a payment under an insurance policy, self-insurance, or otherwise, for the benefit of a health care practitioner in settlement of or in satisfaction in whole or in part of a claim or a judgment against such health care practitioner for medical malpractice, must report information as set forth in paragraph (b) of this section to the NPDB and to the appropriate state licensing board(s) in the state in which the act or omission upon which the medical malpractice claim was based. For purposes of this section, the waiver of an outstanding debt is not construed as a ''payment'' and is not required to be reported.

(b) *What information must be reported.* Entities described in paragraph (a) of this section must report the following information: